United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Pesticide Data Program

SOP No.: PDP-DATA-06	Page 1 of 6	
Title: Data Review Requirements		
Revision: Original	Replaces: N/A	Effective: 09/01/99

1. Purpose:

To provide standard procedures for data review by USDA/AMS Pesticide Data Program (PDP) participating facilities.

2. Scope:

This standard operating procedure (SOP) shall be followed by all laboratories conducting residue studies for PDP, including support laboratories conducting stability or other types of studies that may impact the program.

3. Outline of Procedures:

5.1 Data Package Contents
5.2 Data Review
5.3 Responsibilities

4. References:

USDA/AMS PDP Quality Assurance Meeting, May 18-20, 1999
Good Laboratory Practices, 40 CFR Part 160, Environmental Protection Agency (EPA)

5. Specific Procedures to be Followed:

This standard operating procedure (SOP) represents minimum PDP requirements and is presented as a general guideline. Each laboratory shall have written procedures that provide specific details concerning how the procedure has been implemented in that laboratory.

5.1 Data Package Contents

Each data package shall contain, at minimum, the following: instrument methods (data acquisition, calibration/standardization, and data analysis parameters); injection sequences; chromatograms of samples, standards, reagent blanks, matrix blanks, and matrix spikes; PDP Sample Information Forms (SIFs); Laboratory Information Forms (LIFs); QA Information Forms (QIFs); and documentation of technical and QA review. Additional elements of the data package shall be at the discretion of the local TPM and QAU.

5.2 Data Review

a. General

1. Chain-of-custody is maintained. Samples are properly logged as specified in PDP-LABOP-01.

2. The data package is clearly labeled with a minimum of year, month, and commodity.

3. All data is legibly recorded in permanent blue or black ink.

4. All errors are corrected using single-line cross out. Each correction is dated, initialed, and annotated as required in PDP-DATA-01.

5. All marker compounds are spiked and meet criteria as specified in PDP-QC-04. Any failure to meet criteria is investigated and documented by the Technical Program Manager or designee per PDP-QC-04.

6. All appropriate QA/QC samples are prepared and meet criteria as specified in PDP-QC-04. Any failure to meet criteria is investigated and documented by the Technical Program Manager or designee per PDP-QC-04.

7. All results are correctly entered and annotated on the QA Information Form (QIF) and Laboratory Information Form (LIF), including BQLs,

presumptive tolerance violations (PTVs), etc.

b. Methods and Sequences

1. All instrument methods and sequences are printed and dated and initialed by the analyst. Exceptions are mass spectrometer methods containing large calibration tables. Exceptions shall be agreed upon by the Technical Program Manager and QAU and shall be documented.

2. Each sequence shall identify the analyst, instrument, column,and unique identifier for that sequence.

3. Calibration data are included and are correctly updated.

c. Standards

1. All standards are traceable. Refer to PDP-STD-01 documentation and coding requirements.

2. All calculations are done using a calibration curve or single-point calculation as specified in PDP-DATA-03, sections 5.2 and 5.3.

3. Calibration integrity is performed as required in PDP-DATA-03. Any failure to meet the specified criteria is documented.

d. Chromatograms

1. All chromatograms are labeled as required in PDP-DATA-01, section 5.3 and PDP-DATA-04, section 5.1. At minimum, the following is included on each chromatogram or cover sheet generated for that analytical run: analyst, instrument, column, method, sequence, commodity, and date of analysis.

2. All reported peaks are correctly identified.

3. UARs are investigated, and if identified, estimated and annotated properly (refer to RDE code list attached to PDP-DATA-02).

4. Retention times are within approved limits.

5. All reprocessed chromatograms and associated reports are clearly labeled.

6. All reinjections, reextractions, etc. are clearly identified and documented.

7. All positive findings are confirmed per PDP-DATA-02.

5.3 Responsibilities

Each data package shall be reviewed, at minimum, as documented in this Standard Operating Procedure (SOP). Each data package shall undergo review by the technical section for accuracy and completeness prior to submission to the QAU (refer to PDP-ADMIN-02 subsection 5.9). Verification of results should be the primary function of QAU; however, QAU shall have access to all documentation necessary to achieve this objective. Both technical and QA reviews shall be documented.

Following QAU review of a data package, that data may not be changed by any laboratory personnel unless as a response to comments/concerns/recommendations by the QAU (refer to PDP-ADMIN-06). All corrective actions taken as a result of QA findings shall be documented.

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Original	1999 QA Meeting , 1999	QA Committee

- Specified data review requirements
- Modified outline of procedures
- Separated document into three parts, data package contents, data review, and responsibilities
- Rearranged document accordingly, taking into account QA meeting agreements
- Added clarification statement to subsection 5.2.b.2